



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DI75B

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

February 7, 1997

Ref: 97-DAL-WL-15

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Suzanne Harper, President
Sisbro International Technologies Inc.
15851 Dallas Parkway, #720
Dallas, TX 75248

Dear Ms. Harper:

On February 6, 1997, the Food and Drug Administration inspected a shipment of mattresses, waist belts, and knee pads imported into the United States by your firm on February 5, 1997 under entry numbers 1530084230-7 and 1530084081-4. The inspection revealed the products were actually class III magnetic medical devices. As an importer and registered distributor of medical devices, your firm is aware that these products are regulated by the Food and Drug Administration and must be properly declared at the time of entry.

Such misrepresentation at the time of entry appears to be an attempt to circumvent FDA's statutory requirement mandating an approved application for Premarket Approval pursuant to Section 515(a) [Adulteration, Section 501(f)(1)(b)] and a medical device listing as required by Section 510(j), [Misbranding, Section 502(o)]

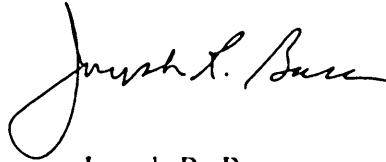
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported product meets all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within (15) days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Page 2 - Ms. Suzzane Harper

Your written response should be addressed to Todd W. Cato, Import Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in cursive script, reading "Joseph R. Baca". The signature is written in dark ink and is positioned above the printed name and title.

Joseph R. Baca
District Director